

# Sharing Data via Established Policies and Procedures in NHLBI Cardiovascular Cohort Studies

Lessons from MESA for  
Environmental Health Research

# Context

- Long History of Cohort Studies at NHLBI
- Major Federal Investments
- Intramural Research Program
- Established Policies and Procedures

# Data Sharing Through at Least Three Mechanisms

- Limited Data Sets
- Investigator-Directed Scientific Collaboration
  - Ancillary Study Processes
  - Publication and Presentation Processes
- Genomics Data Sharing
  - dbGaP
  - Genomics Consortia

# Limited Data Sets

- Publicly available
  - [biolincc.nhlbi.nih.gov](http://biolincc.nhlbi.nih.gov)
- Limited individual-level covariates
  - Does have quite a bit of information
- No tradition of including “environmental” exposure information

**Data Set Name: mesae1eventsdres10012008.sas7bdat**

Obs	Num	Variable	Type	Len	Pos	Format	Label
1	12	ang	Num	8	64	ANG.	Angina Pectoris
2	14	angtt	Num	8	72		Time to Angina or last follow-up (days)
3	13	angtyp	Char	8	416		Angina type
4	18	cbg	Num	8	96	CBG.	Coronary Bypass Graft (CBG)
5	20	cbgtt	Num	8	104		Time to CBG or last follow-up (days)
6	19	cbgtype	Char	8	432		CBG type
7	39	chda	Num	8	240	CHDA.	Coronary Heart Disease (CHD), All

**Data Set Name: mesae1dietdres12042007.sas7bdat**

Obs	Num	Variable	Type	Len	Pos	Format	Label
1	1	MESAIID	Num	8	0		MESA Participant Identification Number
2	370	addqaddsalt1	Num	8	2952	ADDQADDS.	Added diet qu:Add table salt
3	416	addqanyother1	Num	8	3320	ADDQANYO.	Added diet qu:Eat any other food
4	374	addqcalciumfort1	Num	8	2984	ADDQCALC.	Added diet qu:Calcium-fortified juice

**Data Set Name: mesae3drepl1182008.sas7bdat**

Obs	Num	Variable	Type	Len	Pos	Format	Label
1	230	a2a3c	Num	8	1832	A2A3C.	Angiotensin type 2 antagonists
2	231	a2ad3c	Num	8	1840	A2AD3C.	Combinations of angiotensin II antagonists plus diuretics
3	206	ab1ynum3	Num	8	1640		# OF TIMES TREATED W/ ANTIBIOTICS, PAST YEAR
4	31	abi3c	Num	8	240		ANKLE-BRACHIAL INDEX
5	232	ace3c	Num	8	1848	ACE3C.	ACE Inhibitors without diuretics
6	233	aced3c	Num	8	1856	ACED3C.	ACE Inhibitors with diuretics
7	234	adpi3c	Num	8	1864	ADPI3C.	Inhibitors of ADP-induced platelet aggregation
8	117	advice3	Num	8	928	ADVICE3F.	IS THERE SOMEONE AVAILABLE TO GIVE YOU GOOD ADVICE ABOUT A PROBLEM?
9	118	affectn3	Num	8	936	AFFECTNA.	IS THERE SOMEONE AVAILABLE TO YOU WHO SHOWS YOU LOVE AND AFFECTION?
10	54	agatp13c	Num	8	424		Scan 1: Total Agatston Calcium Score, Phantom Adjusted

# Investigator-Directed Scientific Collaboration

- Ancillary Study Processes
- Publication and Presentation Processes
- Anticipate a sponsor from the existing group of investigators
- Review by standing committee and by cohort steering committee
  - Ensure scientific merit
  - Discourage overlap / competitive projects
  - Limit participant and staff burden
  - Engage proper collaborators within cohort's investigative team
    - Insures proper credit to investigators who created the resource
    - Avoids inappropriate use of datasets unfamiliar with details of the population under study
  - Permit data sharing after reasonable opportunity for publication by investigator leading analysis or generating new data
  - DMDA

# Genomics Data Sharing

- dbGaP
- Cross-cohort consortia (e.g., CHARGE)

# Data Use Agreements

- Data Distribution Agreement for Affiliated Investigators
- Data and Materials Distribution Agreement for Collaborating Investigators (with local IRB approval)



# MESA Air

- Data Sharing As Two-Way Street
- Joining MESA community of investigators
- Strategies to properly share efforts with other investigators

# MESA Air experience

- Worked within MESA Ancillary Studies Process
- Extraordinary investment in this project
- Know background of re-analysis challenges to prior work in this field
- Limits of participant consent
- We re-consented all for our planned work
- Tiered consent for geocoding work, genetic studies, and monitoring activities

# Our Approach

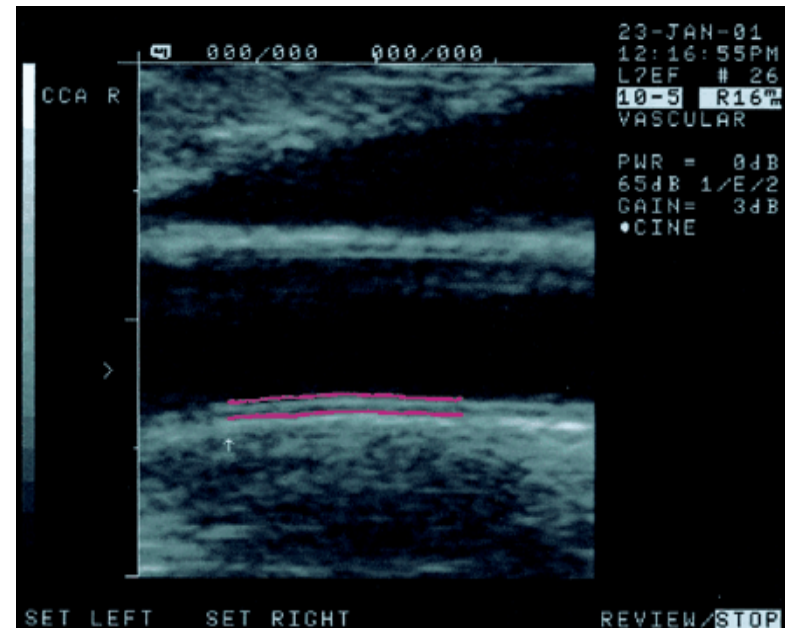
- Pair state-of-the-art cardiovascular epidemiology with state-of-the-art exposure estimation
  - Unusual dedication of resources
- Encourage extensive collaborations and promote opportunities for ancillary studies
  - MESA Air as research platform

# Adjudicated Clinical Events

- Myocardial Infarction
- Stroke/TIA
- Congestive Heart Failure
- Coronary Revascularization
  - PTCA
  - CABG
- Angina
- Peripheral Vascular Disease
- Cardiovascular Death

# Primary Subclinical Outcomes

- Coronary Artery Calcium (CAC)
- Carotid Artery Intima Medial Thickness (IMT)

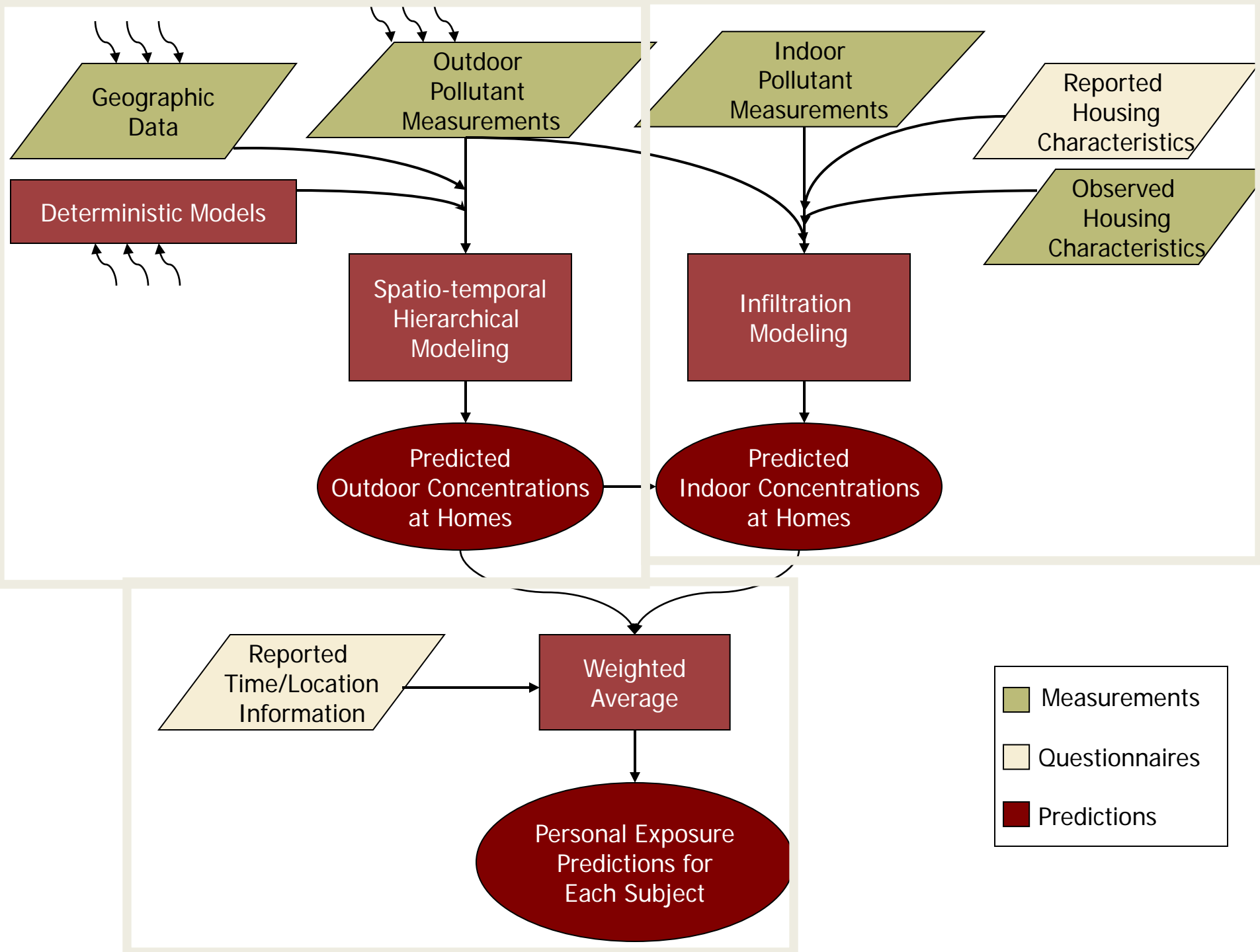


# Extensive Interview Data

- Medical History
- Medications
- Personal History
- Family History
- Health and Life
- Physical Activity
- Diet
- Neighborhood Characteristics
- Residential History
- Sleep History
- Cognitive Assessment

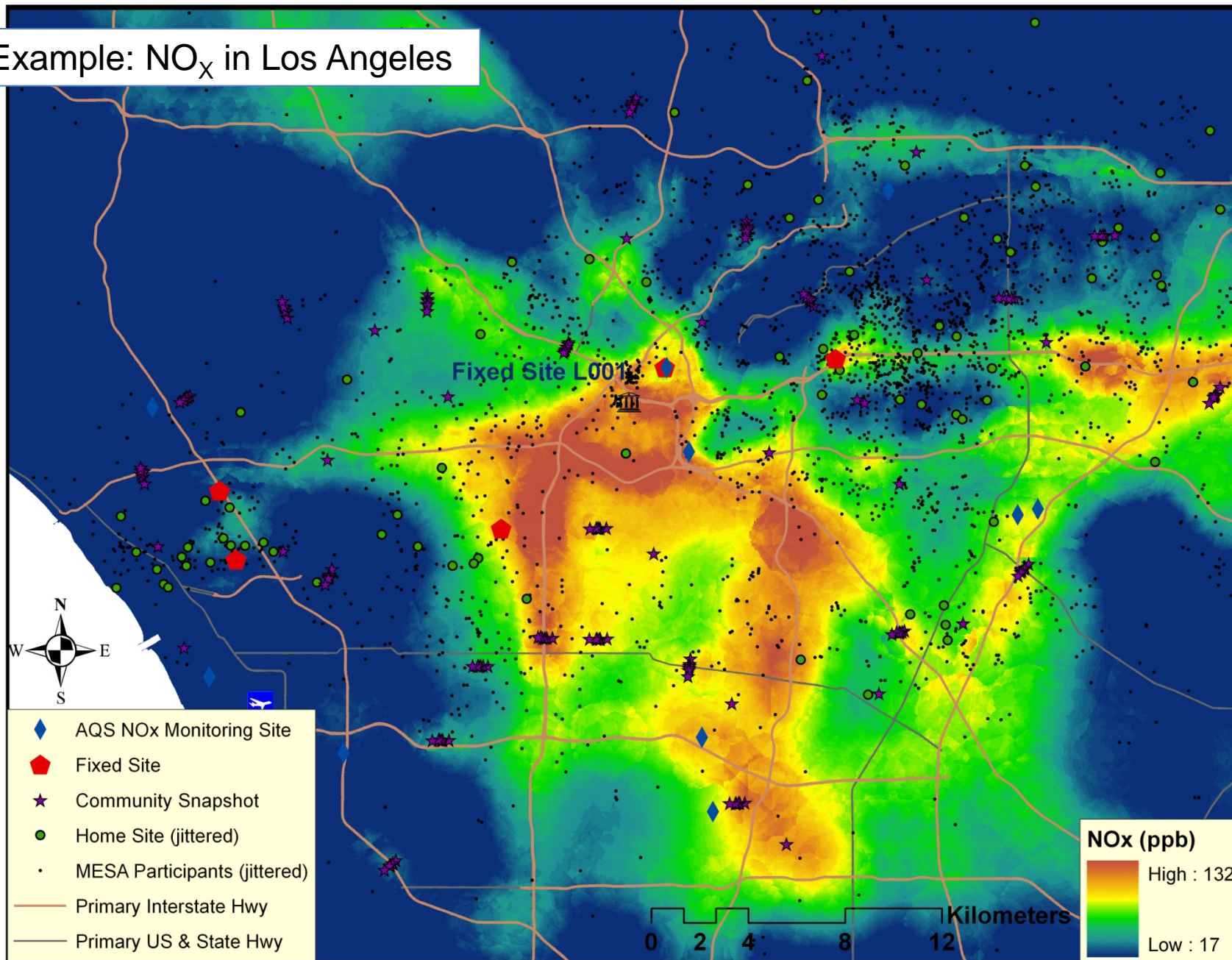
# Other Measures and Specimens

- Anthropometry
- Resting Blood Pressure
- Ankle/Brachial Blood Pressure Index
- ECG
- Spirometry (MESA Lung)
- Cardiac MRI
- Retinal Photography (MESA Eye)
- Quantitative Lung CTs (MESA Lung)
- Urine Collection
- Blood Collection
- Genomics/Epigenomics
  - MESA Family
  - Candidate Genes
  - CArE
  - SHARe
  - DNA methylation
  - Gene Expression



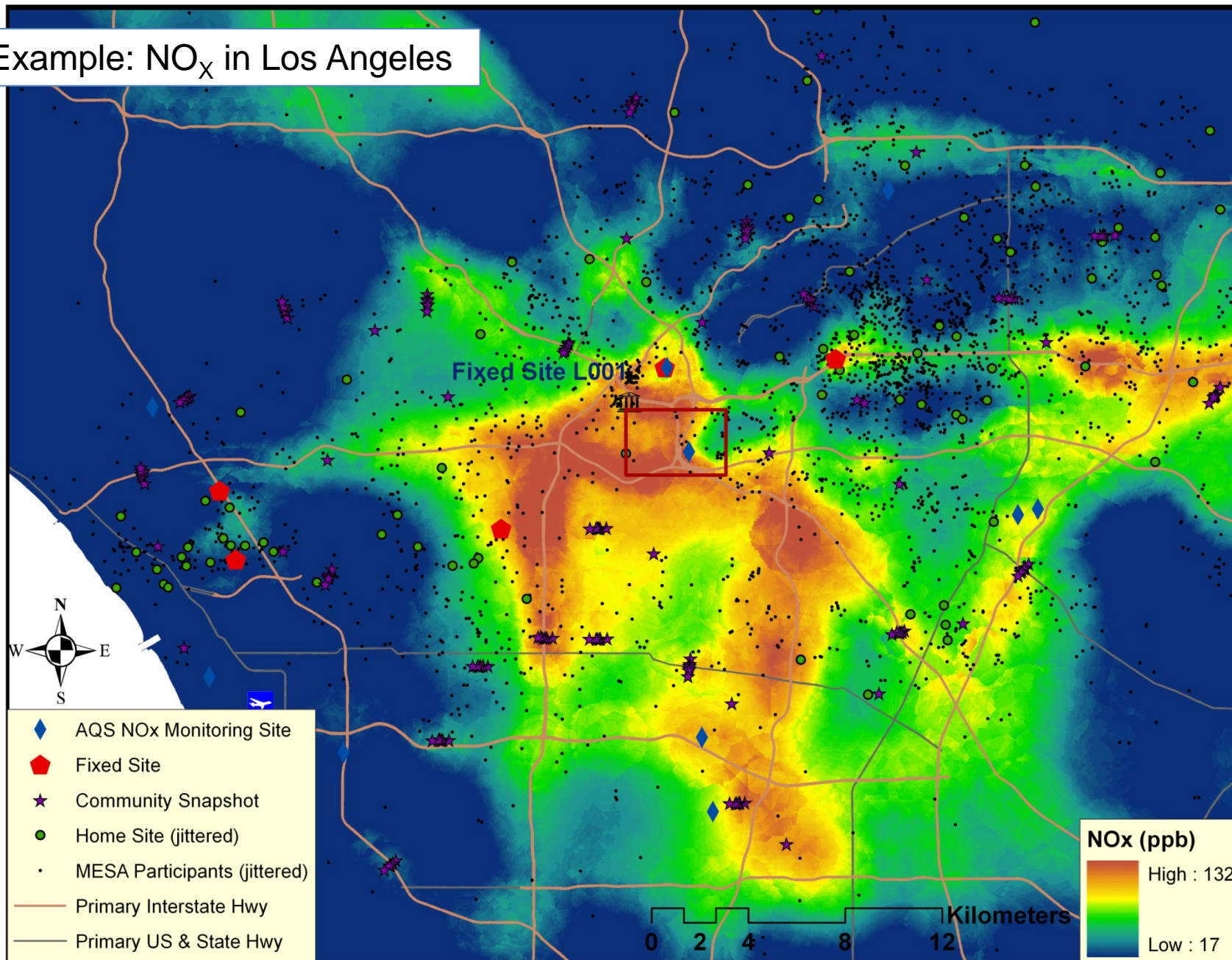


## Example: NO<sub>x</sub> in Los Angeles

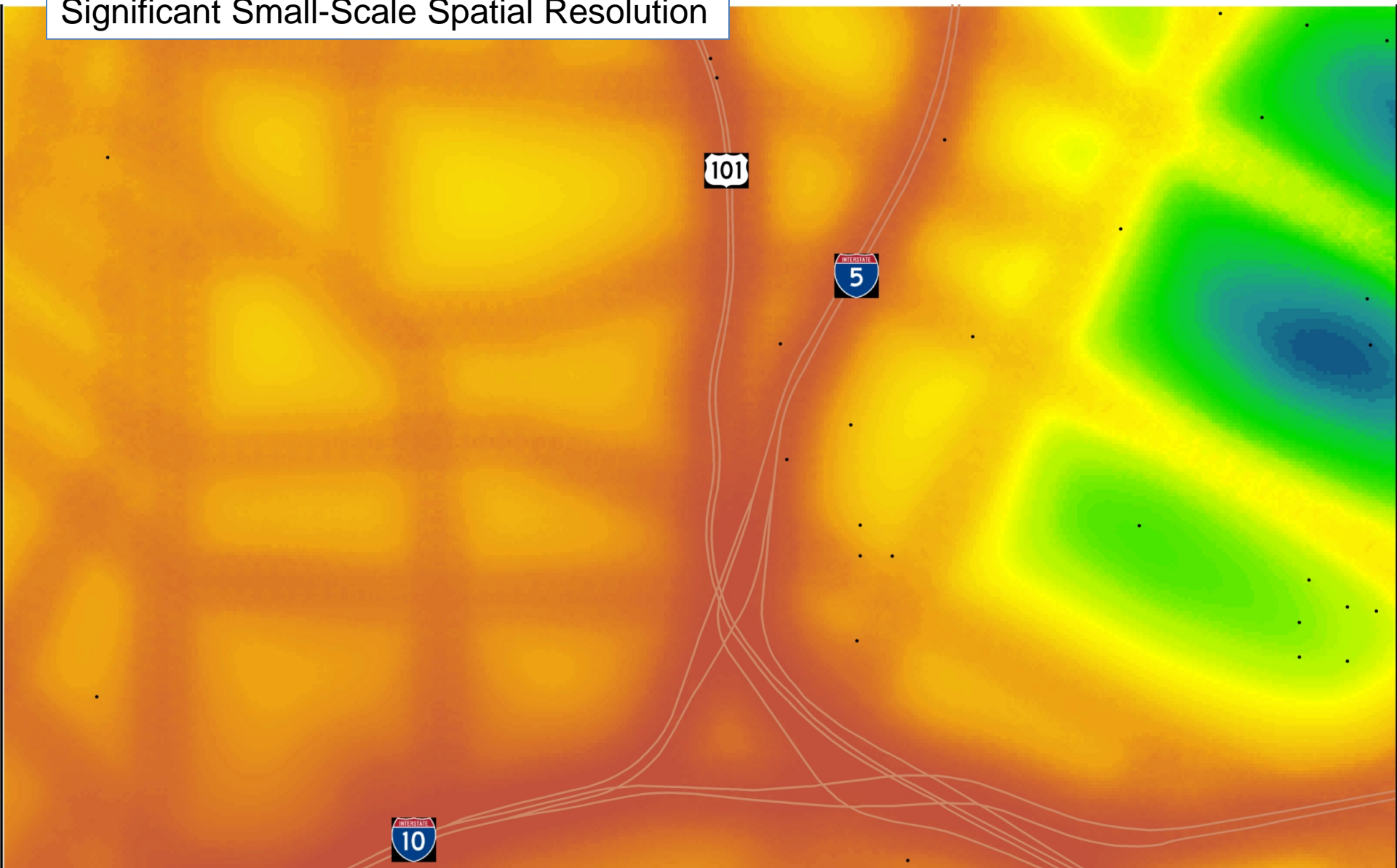




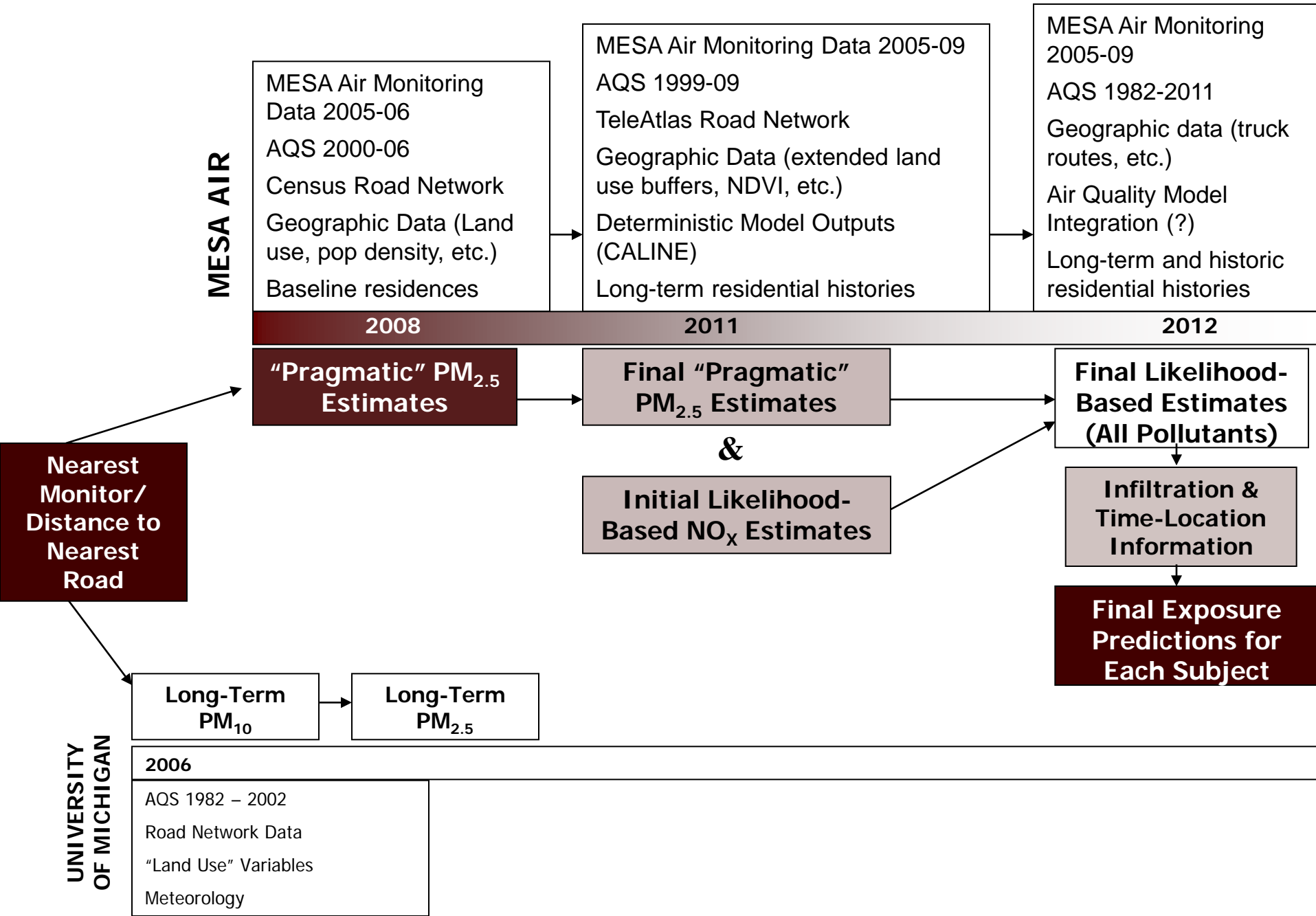
## Example: NO<sub>x</sub> in Los Angeles



## Significant Small-Scale Spatial Resolution



# Spatio-Temporal Exposure Modeling Estimates





# Special issues

- Recognition that participant residence locations must be protected as with other identifiers
- MESA has sample repository
- Created MESA Environmental Health Working Group, fostering EHS research projects other than air pollution
  - New investigators welcome

# Geographic Data

- Can't release actual participant locations
- Linkage options

# Principles we follow

- MESA Air is an unusual dedication of resources and data-sharing is expected
- Precise geocoding is identifying of participants and must be treated like other identifying information
- Exposure data we generate needs to be well-documented and quality-assured so that endusers can use appropriately. Develop analytical recommendations

# MESA Air P&P process

- Formal data request process for exposure information
  - Relies on approved manuscript proposal



# Participation in SHARe

- MESA Air is full partner
- Sharing environmental data to dbGaP as finalized, as appropriate
- NIH: “Secondary data users not conducting human subjects research” (?)

## MESA SHARE - Data

---

### Applying for access to MESA SHARE Data on dbGaP

MESA Investigators who wish to access MESA SHARE data must submit an application to dbGaP on behalf of their institution. Each institution must submit their own application that lists all MESA Investigators from that site. Investigators who are not listed on the application may not have access to the raw MESA SHARE data. Please contact Kayleen Williams at [kmfw@uw.edu](mailto:kmfw@uw.edu) for application instructions and template materials.

### MESA Data included in MESA SHARE on dbGaP

All phenotype variables must be submitted to dbGaP via the CC before they can be analyzed with the GWAS data. Ancillary study PIs who would like to add their data to dbGaP should contact Kayleen Williams at [kmfw@uw.edu](mailto:kmfw@uw.edu).

#### Version 1 – Released March 2010

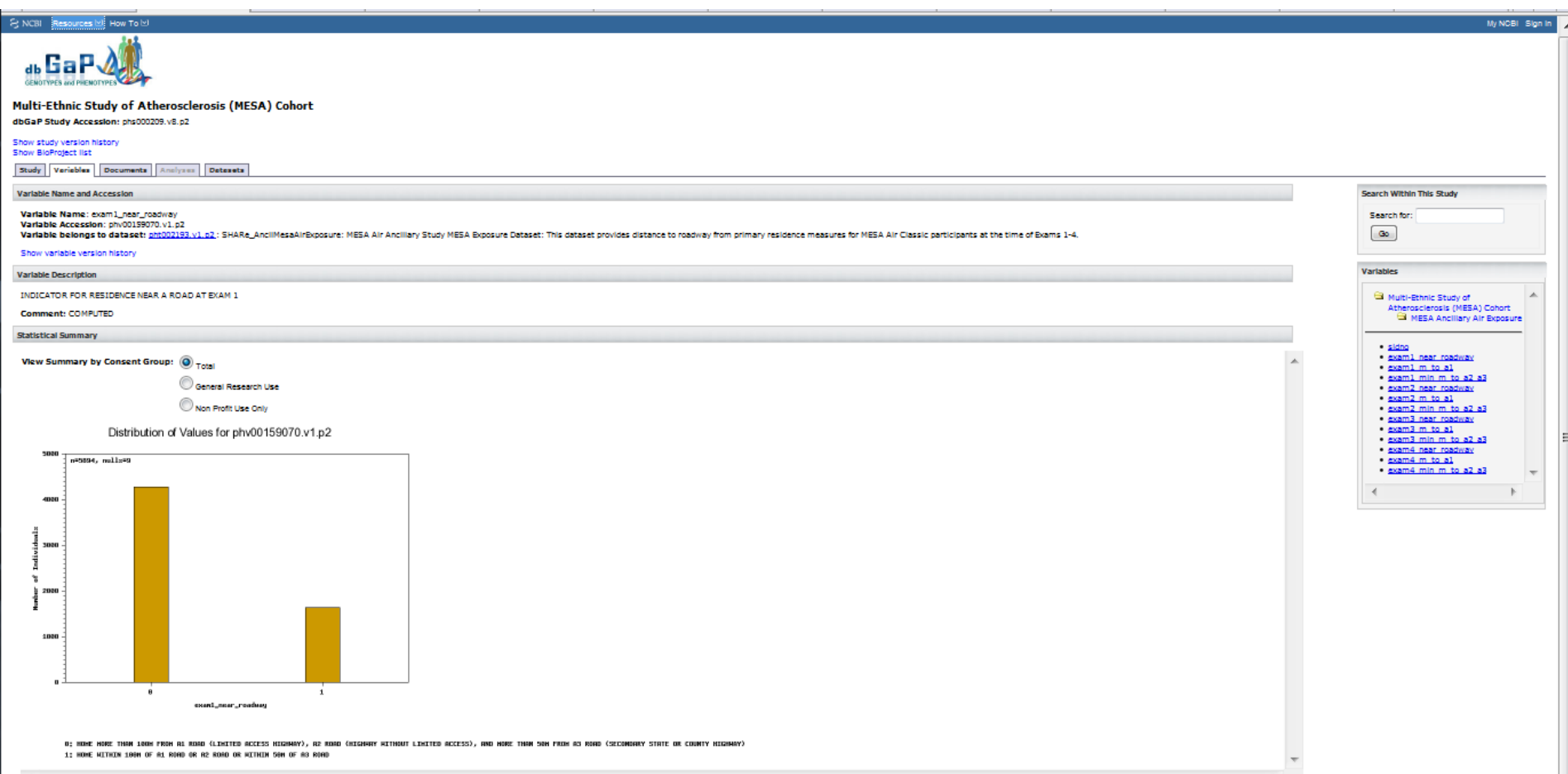
- MESA Classic Exams 1-4
- Events through Follow Up 7
- MESA Family Exam
- MESA Air New Recruits Exam
- MESA Lung Spirometry
- Abdominal Aortic CT data

#### Version 2 – Released May 2010

- Adiponectin
- Aortic Valvular Calcium
- Exam 3 and Exam 4 Abdominal Aortic CT
- FMD
- Pericardial Fat
- Sex Hormone
- Sphingomyelin
- Atrial Fibrillation Events

#### Version 3 – Released August 2010

# dbGaP MESA SHARe



# Next steps

- Data Linkages that remove all concerns?
- Collaborations through MESA Environmental Health Working Group
- Ongoing collaborations
- Preparation for reanalysis requests?